

REMARKS

The present application relates to a method of treating or inhibiting the growth of cancer cells by administering certain substituted triazolopyrimidines.

Claims 2-4, 6-8, 10-12, 14-15, 17-20, 22, 67, 74-77, 79-81, 83-85, 87-88, 90-93 and 95-99 are pending in the application.

Claims 2-3, 14, 18, 20, 22, 98 and 99 have been amended.

Claims 8, 12, 17, 67, 74-77, 79-81, 83-85, 87-88, 90-93, 95 and 97 have been canceled.

In the office communication of February 23, 2007 the Examiner has retained the rejection of claims 2-4, 6, 10-11, 14-15, 18-20, 22, 67, 96, 98 and 99 under 35 USC §112, first paragraph, as failing to comply with the enablement requirement. Applicants believe that the Examiner intended to also include claim 7.

Applicants have amended the claims to limit R¹ to -NR^aR^b and to also limit the kinds of cancers claimed to those cancers for which testing data is presented in the specification.

Applicants have amended the claims to the kinds of cancers tested so the scope of the claims, the testing methods and guidance thereto provides the skilled oncologist with sufficient teaching and guidance. The activity of compounds as exemplified in the specification provides the testing results of many different tumor cell lines which include human cell lines and in vitro and in vivo testing data.

The Examiner has questioned the activity of examples #231-269 of the specification.

Applicants in answer to the Examiner's statements that examples 231-269 do not appear to have activity have provided herewith an Affidavit under 37 CFR 1.132 from CARL F. BEYER which establishes that examples 231-269 of the instant invention have cytotoxic activity as shown using the MTS assay on COLO 205 human adenocarcinoma cells. Exhibit 1 of the Affidavit presents the results of the MTS assay for examples 231-269. Applicants respectfully direct the Examiner's attention to the Affidavit for further details thereof.

Results of this standard pharmacological test procedure for determining cytotoxic activities are presented in Table 2 of the specification, either as an IC₅₀ determination using six concentrations of test compounds (compounds 1-230), or as percentage of control proliferation when tested at two concentrations (compounds 231-269). The percentage of control at either or both 25 and 50 micrograms/mL of a test compound when less than 100, determines that the compound was strongly cytotoxic for the cells at either or both concentrations. Therefore, applicants believe that the specification provides the skilled oncologist with sufficient direction and guidance.

Applicants have provided a series of compounds for a new use in oncology. As stated by the Examiner, the art does not provide teaching as to the method of using the [1,2,4]triazolo[1,5-a]pyrimidine compounds in oncology. Applicants have, however, provided to the skilled oncologist a specification with diverse tumor cell testing, including in vivo testing which teaches the full scope of the claimed method of use and provides said oncologist with a choice of an effective compound. Applicants believe they have advanced the art by providing to the art [1,2,4]triazolo[1,5-a]pyrimidine compounds for use in oncology.

Applicants' specification provides sufficient teaching to the skilled oncologist by providing diverse tumor cell testing, including in vivo testing which provides sufficient guidance as in vitro testing and additional in vivo testing to support the therapeutic oncology utility and therefore no further testing or undue experimentation is required by the skilled oncologist to practice the invention.

The Examiner has stated that the compounds of invention do not seem to have cytotoxic activity and thus one skilled in the art would have to conduct both in vitro and in vivo assays to determine effective compounds. Applicants fully traverse this statement and refer the Examiner to the numerous tables of in vitro cell line data, including human cell lines in the specification which provide more than sufficient support for the treatment of cancer. Additionally, applicants have provided in vivo data in the form of human tumors in nude mice which are acceptable models for addressing the cytotoxic activity of compounds. Furthermore, the Affidavit presented herewith provides evidence that the compounds are cytotoxic.

For all the foregoing reasons, Applicants respectfully traverse the rejection under 35 U.S.C. § 112, first paragraph and assert that the claims as amended are fully enabled. The Applicants further assert that, given the scope of the amended claims, and the extent of the disclosure, undue experimentation would not be required to make or use the invention in its full scope. The Applicants assert that the scope of the claims as amended bear a significant correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph.

In summary, for the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the grounds for rejection set forth in the February 23, 2007 Office Action and earnestly solicit allowance of the claims now pending.

Respectfully submitted,



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